Global Agriculture Information Network

Voluntary Report - public distribution

GAIN Report #E23032

Date: 3/7/2003

# European Union Sanitary/Phytosanitary/Food Safety EU Feed and Food Controls 2003

Approved by:

Norval E. Francis U.S. Mission to the European Union, Brussels

Prepared by:

Gerda Vandercammen

# **Report Highlights:**

The European Commission released its long awaited proposal for a harmonized regulation on feed and food controls. This is a framework regulation establishing the legal basis for all future feed and food controls, including import controls.

**SUMMARY**. Early February, the European Commission released its long awaited proposal for a harmonized regulation on food and feed controls (COM(2003)52 final). This proposal is intended to replace the patchy and fragmented control systems that are currently in place. It brings all food and feed from production stage until consumption under the same umbrella and mirrors many of the principles and requirements in place for animal-origin products (border inspection posts, fees, control plans, listed countries) to food and feed of non-animal origin.

This proposal could have serious impact on U.S. feed and food exports. The proposal provides for the possibility of requiring transshipments going though the EU to comply with EU food safety regulations. It also calls for third countries to have the same or equivalent controls in place in order to ship to the EU. For third countries with which the EU has equivalency agreements, including the U.S., the EU will perform a general comprehensive audit of each of these countries which would cover the main sectors which export products to the EU.

The proposal is under the co-decision process of the EU, that is agreement between both the Council and the European Parliament. Therefore, the proposal as it stands now could see major revisions. The process will take at least a year, as implementation is scheduled for January 1, 2005. Commissioner Byrne presented the proposal to the Agricultural Council during their meeting on February 20. The proposal will now go to the European Parliament for review during the second quarter of 2003. The proposal was notified to the WTO earlier this week; the deadline for comments is May 3.

After review of the proposal, post encourages U.S. industries and affected regulatory agencies (FDA, FSIS, APHIS, GIPSA) to provide input to post on specific points in the proposal which could be difficult to implement. The full text of this proposal can be found on the web at http://europa.eu.int/eur-lex/en/com/pdf/2003/com2003\_0052en01.pdf

**OVERVIEW.** The proposal is complementary to Regulation 178/2002 which created a general EU food law and establishing the European Food Safety Agency (EFSA). It provides for a harmonized EU-wide approach to the design and development of member state food and feed control systems, a common approach to imports of food and feed, general audits of national and third country control systems, technical assistance to developing third countries and administrative and criminal sanctions for non-compliance with food and feed law.

Of particular importance for U.S. exporters are the provisions of articles 14-25 on the controls on the introduction of food and feed from third countries. Under this chapter, it is proposed to establish at Community level a list of priority feed and foodstuffs for which experience has shown that hazards may occur (e.g. aflatoxins in certain foods). Such feed and food shall be presented at specially designated and equipped inspection posts for carrying out the necessary checks. The proposal furthermore provides for the possibility of controls and for additional rules to be adopted in the implementation stage on food and feed from third countries that enters into free zones and free warehouses or is placed in transit. The competent authority will take a decision on the destination of food or feed consignments not complying with feed or food law. There are basically three options: the consignment will be either be seized and destroyed, brought in compliance through a treatment or re-dispatched to a third country or the country of origin. In

the case of re-dispatch the competent authorities of the country of destination has to expressly agree to receive the consignment. Re-dispatch has to take place within 60 days after the competent authority submits its decision to the business operator. If re-dispatch is found impossible after 60 days, the consignment will be destroyed.

Article 46 addresses the issue of community controls in third counties. Third countries will be required to have control plans available, similar to those foreseen for the Member States, in respect of the products they export to the EU. These plans will form the basis for the Community audits in third countries which will either verify compliance or equivalence of third country legislation and systems with Community food and feed law, and Community animal health legislation.

The proposal should become applicable from 1 January 2005, at the same time the general food law requirements enter into force. However, implementation of some of the requirements of the regulation are already under consideration. As an example, the Standing Committee on the Food Chain and Animal Health put an exchange of views on a draft harmonized model for the annual report on official feed controls on its March 19 agenda.

The full impact of this new regulation will only become visible at the implementation stage. As a general rule, the implementation legislation will be developed by the Commission in cooperation with the member States in the Committee on the Food Chain and Animal Health.

#### OTHER REFERENCE DOCUMENTS

The Commission also prepared a Questions and Answers document available form the RAPID database at: <a href="http://europa.eu.int/rapid/start/welcome.htm">http://europa.eu.int/rapid/start/welcome.htm</a>. Search for MEMO/03/24

#### ANALYSIS OF THE PROPOSAL

# TITLE I - SUBJECT MATTER, SCOPE AND DEFINITIONS (art 1-2)

This regulation establishes the general rules for the performance of official controls on food and feed. The aim of this regulation is to prevent risks to humans and animal and to protect consumer interest.

#### TITLE II - OFFICIAL CONTROLS BY MEMBER STATES

Chapter I: General Obligations (art 3)

Official food and feed controls shall be carried out regularly and must be risk based. They must cover the entire food chain.

# Chapter II: The competent authorities (art 4-10)

The proposal defines operational criteria for the competent authorities in charge of official food safety controls. The Commissions's Food and Veterinary Office will organize audits to verify the effectiveness of national control systems. Specific control tasks may be delegated to an independent body under strict conditions. The staff of the competent authorities needs to receive regular training and have access to procedures and guidelines.

Chapter III: Sampling and analysis (art11-12)

Methods of sampling and analysis have to be validated in accordance with Community

legislation or internationally accepted protocols and must be carried out by laboratories accredited for that purpose.

Chapter IV: Crisis management (art 13)

Member States have to draw up contingency plans setting out the measures to be implemented in case of food and feed emergencies.

Chapter V: Controls on the introduction of feed and food from third countries (art 14-25) The proposal introduces a harmonized approach to import controls of food and feed of non-animal origin, in order to achieve a consistent approach with the currently existing controls for food and feed of animal origin. Controls can take place at any time of the distribution of the goods: before release into free circulation or afterwards, e.g. at the importer's premises, during processing or at the retail level.

In addition, it is proposed to establish at Community level a list of priority feed and foodstuffs for which experience has shown that hazards may occur (e.g. aflatoxins in certain foods). Such feed and food shall be presented at specially designated and equipped inspection posts for carrying out the necessary checks. These controls must be carried out before the goods are released for free circulation.

The proposal furthermore provides for the possibility of controls on food and feed from third countries that enters into free zones and free warehouses or is placed in transit, customs warehousing, or imported under inward processing arrangements.

The competent authority will take a decision on the destination of food or feed consignments not complying with feed or food law in consultation with the feed or food business operators responsible for the consignment. There are basically three options: the consignment will be either be seized and destroyed, submitted to a special treatment or re-dispatched to a third country or the country of origin. The special treatment (option 2) has to bring the consignment in line with Community law or with the requirements of a destination country outside the EU or process the goods for a non-food or feed purpose. In the case of re-dispatch (option 3) the competent authorities of the country of destination has to expressly agree to receive the consignment. Re-dispatch has to take place within 60 days after the competent authority submits its decision to the business operator. If re-dispatch is found impossible after 60 days, the consignment will be destroyed. The feed and food business operator responsible for the consignment or his representative, will be liable for the costs incurred in the process of a special treatment, re-dispatch, destruction or storage under supervision of the competent authority of the consignment.

The proposal provides for the approval in the implementation stage by the Standing Committee on the Food Chain and Animal Health of pre-export checks by third countries. In this case, the frequency of import controls may be adapted. Approvals will include a model for the certificate that third country competent authorities or control bodies will issue for consignments that have undergone a pre-export check.

The proposal foresees for the development of detailed rules for the uniform implementation of

controls in the implementation stage by the Standing Committee on the Food Chain and Animal Health for food and feed handled in free zones or warehouses or placed under special customs procedures such as transit and for the development of detailed rules on food for the supply of or carried by the crew and passengers of international carriers.

# Chapter VI: Financing of Official Controls (art 26-29)

Member States must ensure that adequate financial resources are available for official controls. However, if non-compliance with EU food and feed law leads to expenses that exceed the normal expenses for routine monitoring, these extra expenses can be charged to the operator responsible for the non-compliance.

As a general principle, member states will collect fees for import controls on feed, food and animals. The proposal specifies the amount of fees applicable to imported meat, fishery products and live animals and provides for the future establishment of import fees upon imports of other food and feed products.

#### Chapter VII: Other Provisions (art 30-31)

The proposal provides for the future adoption of certification requirements such as electronic certification and for procedures for registration of establishments as required by the hygiene directive that is currently under discussion.

# TITLE III - REFERENCE LABORATORIES (art 32-33)

The proposal defines the responsibilities of the Community Reference Laboratories (CRL's) and establishes the procedures ensuring that the existing CRL's covering residue testing, milk testing, biotoxins in molluscs, viruses in molluscan shellfish, salmonella and TSE's can continue their work. The proposal also provides for the establishment of additional Community Reference laboratories.

#### TITLE IV - ADMINISTRATIVE ASSISTANCE AND COOPERATION (art 34-41)

The proposal establishes the principles for a uniform system of assistance and co-operation between the controlling authorities of EU Member States. For this purpose, each Member State shall designate a liaison body. When a competent authority becomes aware of non-compliance with food or feed law, and such non-compliance may have implications for other Member States, it has to pass this information on to the other Member States without prior request and without delay.

# TITLE V - CONTROL PLANS (art 42-44)

Member States are obliged to draw up multi-annual national control plans containing general information on the structure and organization of food and feed controls, animal health and welfare systems. Guidelines for the establishment of the control plans are provided. Member States have to submit annual reports to the Commission on the results of the controls and audits, including the number of infringements that have been established. The Commission will use this information for its audit report that it has to submit to the European Parliament and the Council.

#### TITLE VI - COMMUNITY ACTIVITIES

Chapter I: Community Controls (art 45-46)

The creation of a single legal basis with the present proposal and the establishment of control plans will allow the Community control services to perform a global and general audit of the Member States' control system, replacing the current fragmented sectoral approach. Third countries will be required to have control plans available, similar to those foreseen for the Member States, in respect of the products they export to the EU. These plans will form the basis for the Community audits in third countries which will either verify compliance or equivalence of third country legislation and systems with Community food and feed law, and Community animal health legislation.

# Chapter II: Import Conditions (art 47-50)

The regulation provides for an expansion to all foods and feed of the current approach used in the animal products sector, with the listing of third countries from which food and feed may be imported and the development of model certificates. Third countries have to provide guarantees that the establishments eligible to export food and feed comply with or are equivalent with Community feed and food law. Establishment lists have to be communicated to the Commission. In the implementing phase of this regulation, the standing Committee for the Food Chain and Animal Health can recognize that third countries provide equivalent guarantees to those applicable in the Community, and set out the import conditions for these countries. Assistance will be provided to developing countries to comply.

# Chapter III: Training of Control Staff (art 51)

The Commission may organize training courses for the staff of competent member state authorities.

# Chapter IV: Other Community Activities (art 52-53)

The Commission has to be involved in third country controls in EU Member States.

#### Title VII - ENFORCEMENT MEASURES

Chapter I: National Enforcement Measures (art 54-55)

Experience has shown that the existing system of mainly administrative sanctions has not always been sufficient to ensure compliance. In the case of non-compliance, proportionate and dissuasive penalties need to be applied. The proposal re-confirms the need for the Member States to take administrative enforcement measures such as product recalls and business closures. Additionally, a series of infringements which, if committed intentionally or through serious negligence, have to be considered as criminal offences. The list is divided up in infringements of legislation on feedingstuffs (e.g. the use of unauthorized feed additives), BSE/TSE, food (e.g. the illegal use of hormones in animals), pesticides, safeguard restrictions (i.e. violation of prohibition to bring food or feed on the market that is subject to emergency measures), animal by-products, animal health (i.e. the failure to notify the presence epizootic diseases)

# Chapter II: Community Enforcement Measures (art 56)

The present proposal allows the Commission to take measures on its own initiative when the Commission has evidence that a member State control system is inadequate. These measures include suspension of imports as well the introduction of special conditions for imports.

TITLE VIII: ADAPTATION OF COMMUNITY LEGISLATION (art 57-61)

Existing Community legislation on official controls on food, animal nutrition, methods of analysis for the official controls, veterinary inspections and fees in the animal feed sector will have to be repealed. Council Directive 96/23/EC on residues will have to be amended to reflect provisions of the feed and food control regulation on the handling of animal and meat shipments containing unauthorized residues. Currently, these shipments have to either be returned to the country of origin or in certain cases, the consignor can decide to send the shipment back or use it for another authorized Community use.

Council Directive 97/78/EC concerning the organization of the veterinary checks on products entering the community will have to be modified to bring it in line with the provisions of the food and feed framework regulation, including provisions on the scope of the regulation to include animal by-products, provisions on food and feed for international carriers, handling of consignments that have not been presented for veterinary checks.

### TITLE IX - GENERAL PROVISIONS (art 62-65)

Implementing legislation will mainly be developed by the Commission with the assistance of the Standing Committee on the Food Chain and Animal Health, or where necessary by the Standing Committee on plant health. A number of the activities introduced by this proposal will be financed by a Community budget.

# TITLE X - FINAL PROVISION (art 66)

The regulation will become applicable from 1 January 2005, at the same time the general food law requirements enter into force.